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**13. ABSTRACT** *(Maximum 200 Words)*

The **purpose** is to evaluate perioperative training for lymphedema assessment and protection. The **hypothesis** is that structured perioperative training in lymphedema protection will decrease lymphedema, the episodes of infection, the time to detection of lymphedema and improve the QOL in patients undergoing axillary dissection and/or radiation therapy for breast cancer as compared to a control group. The **specific questions (scope)** are 1) what is the incidence of lymphedema and infection during the first three years after surgery among breast cancer patients who received perioperative training in lymphedema protection as compared to a control group? 2) What are the differences in the measured QOL among breast cancer patients during the first three years after surgery that received perioperative education in lymphedema protection as compared to a control group? 3) What are the retention of information on lymphedema protection, and the compliance with arm precautions among breast cancer patients who received perioperative lymphedema training as compared to a control group? **Major Findings:** During the first 21.5 months of the study, the incidence of lymphedema was 32.9% overall with 40% in the intervention group as compared to 26.8% in the control group. The QOL measures for the intervention group decreased thus far as compared to the control group. The knowledge scores on lymphedema protection were comparable between the two groups. **Significance:** The lymphedema rate observed overall thus far, and including acute and chronic lymphedema, is greater than reported in the literature. With a decrease in QOL scores and the same knowledge of lymphedema protection, additional analyses may show other influences on the use of the lymphedema protection knowledge, which may impact lymphedema occurrence. This may shift established practice in lymphedema prevention and detection for breast cancer survivors.

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## Table of Contents

## INTRODUCTION

**Reviewer's comments from Year I report:**

1. Define acronyms with initial use.
   **Acronyms are defined with initial use in this Year II report.**
2. Individual bulleted Key Research Accomplishments (KRAs) should not include discussion or represent more than one accomplishment.
   **In this Year II report, individual bulleted KRAs do not include discussion or represent more than one accomplishment.**
3. The Conclusion section represents KRAs or discussion. For the next Annual Report, the PI should consider a separate discussion section.
   **A separate Discussion section is placed after bulleted KRAs in this Year II report.**

**Subject:** Increasing numbers of breast cancer survivors are at risk for long-term sequelae from treatment. Axillary surgery or radiation therapy to the breast may alter lymph channels, leaving the survivor with a lifetime risk for developing lymphedema. Lymphedema is a swelling of the upper extremity, which causes pain, debility, and reduced quality of life (QOL) that impacts choices about work, social and sexual interactions and self-esteem. Protective measures to reduce the risk of lymphedema become important life-long skills. However, there is inconsistent teaching of protective measures, and inattention to lymphedema detection in clinical practice. **Purpose:** The purpose of this study is to evaluate perioperative training for lymphedema assessment and protection. The **hypothesis** is that structured perioperative training in lymphedema protection will decrease lymphedema, the episodes of infection, the time to detection of lymphedema and improve the QOL in patients undergoing axillary dissection and/or radiation therapy for breast cancer as compared to a control group. **Scope:** The **specific questions** are 1) what is the incidence of lymphedema and infection during the first three years after surgery among breast cancer patients who received perioperative training in lymphedema protection as compared to a control group? 2) What are the differences in the measured QOL among breast cancer patients during the first three years after surgery that received perioperative education in lymphedema protection as compared to a control group? 3) What are the retention of information on lymphedema protection, and the compliance with arm precautions among breast cancer patients who received perioperative lymphedema training as compared to a control group? **Methods:** Patients with resectable breast cancer also undergoing axillary lymph node surgery and/or radiation therapy to the breast will be prospectively randomized to two groups. In addition to receiving standard care (i.e., written breast rehabilitation materials and preoperative counseling by the breast surgeon), patients in Group 1, will receive structured education in Breast Surgery Rehabilitation including range of motion exercises, lymphedema arm precautions, and management of complications. Patients in Group 2 will receive standard care (written material and preoperative counseling by the surgeon). For both groups, preoperative and then quarterly volume measurements and exams of the upper extremities will be done for three years after surgery in order to determine lymphedema and infection incidence. The QOL will be measured longitudinally by the Functional Assessment of Cancer Therapy-Breast (FACT-B) and the Medical Outcome Study Short Form Health Survey (MOS SF-36) and sexuality subscales of Cancer Rehabilitation Evaluation System (CARES). The knowledge of and practice of lymphedema protective skills will be measured by periodic testing longitudinally as well.

## BODY

**Research accomplishments associated with each task outlined in the approved Statement of Work. Therefore, the Year II report is cumulative.**

**Statement of Work**

*Task 1.* Start-up, Months 1-2.

a. Prepare copies of knowledge and compliance questionnaires, QOL surveys, clinical assessment forms, consent forms, education curricula and radiation database.
**This was completely accomplished.**

b. Prepare accounts for patient incentives, supplies, salaries, and all other budget categories.
**This was completely accomplished.**

c. Train research assistants in arm measurements, ROM, grip strength and clinical assessment of upper extremities, and administering the QOL questionnaires.
**This was completely accomplished.**

d. Prepare class schedule and reserve classroom.
**This was completely accomplished.**

e. Order information books to be passed out to all participants.
**This was completely accomplished.**

f. Organize office for research assistants with locked cabinet, log book, computer, printer, copier and office supplies.
**This was completely accomplished.**

g. Prepare randomization schedule with biostatistician.
**This was completely accomplished.**

h. Set-up data entry with Psychosocial and Behavioral Oncology Core.
**This was accomplished with part-time data manager in secure office in same building as PI.**

**Plan: Increase role of data manager due to complexity of data entry and coordination of information in longitudinal study.**

i. Prepare program for calculation of limb volumes.
**This was completely accomplished.**

*Task 2.* Introduce study to physicians, nurses and clerks in clinics, Months 1-2.
**This was completely accomplished.**

*Task 3.* Subject recruitment and data collection, Months 3-60.

a. Enroll preoperative patients, obtain consent forms, randomize, conduct initial examinations and measurements, clinical data base including Omega Screening Questionnaire (OSQ), QOL instruments (FACT-B, MOS SF-36, CARES).

1. Enrollment should occur during Months 3-27 for a total of 176 subjects.

**The human subjects approval occurred in mid-October, 2000. With 21.5 months of accrual time for this report, 157 subjects were the target. There were 113 subjects accrued, with five (4.4%) who dropped out of study leaving 108 evaluable patients.**

**Thus, the accrual was 72% of target and evaluable subjects was 77% of target. In 2002, the Breast Center lost 2 breast surgeons, which reduced the number of surgical cases. The new director of Karmanos Cancer Institute will be on-site 9/1/02. It is expected that hiring of new breast surgeons will occur shortly. However, this requires additional accrual time while the longitudinal followup continues with subjects already enrolled. Therefore, the study site should be able to continue to accrue subjects. In Table 1, some study subject characteristics are summarized showing mean age, gender, race, stage of breast cancer and broad category of type of surgery performed.**

2. Since enrollment will be staggered, the follow-up period of three years will end at different time points for individual subjects.

**No one has yet reached 3 years of followup.**

3. Subjects randomized to Group 2 (control) will complete a knowledge questionnaire at first post-op visit.

**This was completely accomplished. Compliance was 100%.**

*Task 4.* Perioperative teaching sessions, Months 3-27.

a. After randomization, subjects in Group 1 will be scheduled to a classroom session with Christine Rymal, MSN, BSN, during the first postoperative visit.

**This was completely accomplished.**

b. At the time of the class session, subjects will complete a knowledge questionnaire as a pretest and posttest.

**This was accomplished.**

*Task 5.* Quarterly measurements of subjects, Months 6-60.

a. Subjects in each group will have upper extremities measured and evaluated. While each subject will be followed for three months postoperatively, measurements for the entire enrollment occur up to 60 months of the study due to the staggered enrollment and follow-up design of the study.

**This was accomplished, however, some subjects did not come each quarter for measurements. We will continue to encourage quarterly measurements, understanding that human subjects may be unable to come each time. For a given subject, during the course of 36 months of followup, there will be 12 opportunities for followup measurements. The Community Outreach Core at Karmanos Cancer Institute is now assisting us in contacting subjects to return for followup visits.**

**Table 1 Study Subject Characteristics (those randomized to groups)***

| | Group 1 (Intervention) *n=35* | Group 2 (Control) *n=41* |
|---|---|---|
| mean age** | 52.0 yrs. | 51.8 yrs. |
| race | | |
| African American | 5 | 9 |
| Caucasian | 9 | 13 |
| Hispanic | 1 | 0 |
| Nat. American | 1 | 0 |
| Oriental | 0 | 0 |
| Other | 2 | 0 |
| Unknown | 1 | 0 |
| Stage | | |
| O | 1 | 4 |
| I | 8 | 7 |
| IIA | 9 | 5 |
| IIB | 6 | 10 |
| IIIA | 1 | 3 |
| IIIB | 0 | 1 |
| IV | 2 | 0 |
| Surgery Type | | |
| Mast. and ax. surgery+ | 19 | 21 |
| Lumpectomy and RT | 1 | 4 |
| Lump.,RT, ax. surgery | 15 | 16 |
| Highest level of education | | |
| Doctorate degree | 2 | 0 |
| Master's degree | 0 | 0 |
| Bachelor's degree | 2 | 3 |
| High school grad/GED | 8 | 9 |
| 8-11 yrs | 1 | 2 |
| less than 8 years | 0 | 0 |
| Marital status | | |
| Married/cohabitating | 8 | 7 |
| Divorced/separated | 0 | 4 |
| Widowed | 1 | 3 |
| Never married | 4 | 1 |
| Annual household income | | |
| <$5,000/yr | 1 | 1 |
| $5,000-$15,000/yr | 1 | 2 |
| $15,001-$30,000/yr | 1 | 2 |
| $30,001-$50,000/yr | 1 | 3 |
| $50,001-$75,000/yr | 3 | 2 |
| >$75,000/yr | 3 | 1 |

* 32 patients have not undergone surgery yet (neoadjuvant chemotherapy) and thus not yet randomized.

** all subjects are female

+ ax. surgery =axillary surgery that includes dissection, sampling, sentinel node biopsy (not separated for this report). Mast. = mastectomy; Lump. = lumpectomy; RT=radiation therapy

**Table 1 (cont'd) Study Subject Characteristics (those randomized to groups)***

| | Group 1 (Intervention) *n=35* | Group 2 (Control) *n=41* |
|---|---|---|
| **Transportation** | | |
| **Drive myself** | **9** | **12** |
| **Driven by someone else** | **3** | **2** |
| **Use public transportation** | **1** | **0** |
| **Other** | **0** | **1** |
| **Religious preference** | | |
| **None** | **0** | **1** |
| **Protestant** | **1** | **3** |
| **Catholic** | **5** | **5** |
| **Buddhist** | **0** | **0** |
| **Jewish** | **1** | **0** |
| **Muslim** | **1** | **0** |
| **Hindu** | **0** | **0** |
| **Eastern Asian** | **0** | **0** |
| **Other** | **5** | **6** |

*** 32 patients have not undergone surgery yet (neoadjuvant chemotherapy) and thus not yet randomized.**
**** all subjects are female**
**+ ax. surgery =axillary surgery that includes dissection, sampling, sentinel node biopsy (not separated for this report). Mast. = mastectomy; Lump. = lumpectomy; RT=radiation therapy**

*Task 6.* QOL questionnaires at 6 months, 1-, 2-, and 3-years postop, Months 9-60.

a. FACT-B, MOS SF-36, and sexuality subscales of CARES will be administered for up to three years after surgery. Up to 60 months may be required to accomplish this in all enrolled subjects.

**This is being accomplished. We will continue to offer the QOL questionnaires at 6, 12, 24 and 36 months of followup. For a given subject, during the course of 36 months of followup, there will be 4 opportunities for followup QOL questionnaires. The Community Outreach Core at Karmanos Cancer Institute is now assisting us in contacting patients to return for followup visits or else mailing out the questionnaires.**

*Task 7.* Booster training session for Group 1 subjects, Months 9-33.

b. Christine Rymal will speak with each subject in Group 1 at the 6-month postoperative session, answering questions and passing out a summary sheet on "Precautions for Lymphedema Risk Reduction."

**(see below)**

c. A knowledge questionnaire will be administered as well as compliance questionnaire to subjects in Group 1 at this time.

**Both of these have been accomplished during the reporting period. It will continue throughout the study until all accrued subjects have gone through 6 months in followup after being randomized postoperatively..**

*Task 8.* Knowledge and compliance questionnaires, Months 9-60.

a. Subjects in Group 2 (control) will complete these questionnaires during their 6 month, 1 year, 2 year and 3 year postoperative follow-up sessions. Theses may occur up to 60 months of the study due to the staggered enrollment and follow-up design of the study. **(see below)**

b. Subjects in Group 1 (intervention) will complete these questionnaires at 1 year, 2 year, and 3-year postoperative follow-up sessions. (They will have completed the 6-month questionnaires with Christine Rymal). These may occur up to 60 months of the study due to the staggered enrollment and follow-up design of the study.

**Both of these are being accomplished during the reporting period. We will continue to offer the knowledge and compliance questionnaires at 6, 12, 24 and 36 months of followup. For a given subject, during the course of 36 months of followup, there will be 4 opportunities for followup knowledge and compliance questionnaires. The Community Outreach Core at Karmanos Cancer Institute is now assisting us in contacting patients to return for followup visits or else mailing out the questionnaires.**

*Task 9.* Calculations of limb volumes and comparison of differences, Months 3-60.

a. Wenlien Wang will calculate limb volumes in a blinded fashion weekly based upon limb measurements obtained by the clinical research assistants.

**This is being accomplished with the data manager now calculating the limb volumes and changes.**

*b.* Serial volume measurements will be recorded on a master sheet for each subject and evidence of lymphedema determined weekly.

**This is being accomplished.**

c. The PI and Christine Rymal will review these calculations weekly.

**This is being accomplished.**

*Task 10.* Quarterly data entry and print out by the Psychosocial and Behavioral Core, Months 3-60.

a. Coded data sheets for limb measurements, QOL questionnaires, knowledge/compliance questionnaires, clinical data will be supplied to data entry personnel at the Core facility. After entry of data, a printout will be provided to the PI.

**This is being accomplished with weekly data entry. Printout occurs quarterly. However, the Psychosocial and Behavioral Core has not been participating due to its own reorganization. Therefore, this is being performed by the data manager.**

*Task 11.* Interim analysis of data after 1 year, 3 years, Months 14-16, 38-40.

a. Dr. Du (biostatistician) will analyze the data. Specifically, the lymphedema rate, infection rate, scores, and trends of serial QOL measures (FACT-B, MOS SF-36, sexuality subscales for CARES), scores on knowledge and compliance questionnaires will be tabulated. PI and Co-PIs will review trends and confirm study objectives.

**There are additional opportunities for data analysis whenever abstracts and presentations are planned. The involvement of the statistical portion of the project has increased. Interim Analysis in Table 2 for the Year II report. Plan: Increase the role of the statistician(s) in the project as more data analyses and presentations are planned.**

**Table 2. Specific interim data for study subjects ***

| | | Group 1 (Intervention) *n=35* | | Group 2 (Control) *n=41* |
|---|---|---|---|---|
| lymphedema | | 14 | | 11 |
| lymphedema rate | | 40% | | 26.8% |
| infection | | 2 | | 1 |
| infection rate | | 5.7% | | 2.4% |
| FACT-B scores# | N | | N | |
| initial (mean) | 33 | 115.73±18.27 | 37 | 103.49±28.00 |
| 6-month (mean) | 26 | 114.47±18.98 | 29 | 108.83±23.08 |
| 12-month (mean) | 19 | 111.34±22.47 | 20 | 114.23±17.10 |
| 24-month (mean) | 4 | 120.25±11.50 | 5 | 115.10±17.36 |
| 36-month (mean) | | N/A | | N/A |
| MOS-SF 36 scores## | | | | |
| initial (mean) | 31 | 45.674±11.02 | 33 | 44.031±10.72 |
| 6-month (mean) | 25 | 43.873±12.17 | 29 | 40.321±9.94 |
| 12-month (mean) | 18 | 44.953±9.58 | 18 | 45.695±9.86 |
| 24-month (mean) | 4 | 51.62±6.45 | 5 | 48.367±10.85 |
| 36-month (mean) | | N/A | | N/A |
| CARES sexuality scores& | | | | |
| initial (mean) | 16 | 47.313±4.06 | 19 | 50.368±3.96 |
| 6-month (mean) | 16 | 47.438±4.38 | 20 | 48.350±5.43 |
| 12-month (mean) | 11 | 47.727±4.24 | 17 | 48.235±5.21 |
| 24-month (mean) | 3 | 47.667±4.16 | 4 | 46.000±4.76 |
| 36-month (mean) | | N/A | | N/A |

* 32 patients enrolled, but have not yet undergone surgery and so not randomized yet

# total FACT-B scores reported here. Subscale analysis and trends for individual subjects will occur with greater length of followup (up to 3 years).

## Physical Functioning Scale reported here. Other subscale reports and trends for individual subjects will occur with greater length of followup (up to 3 years).

& T-score for sexuality subscale which converts global score into standardized format.

**TRENDS: Within the first 21.5 months of accrual, there have been 25 patients diagnosed with lymphedema (32.9% overall;25/76 randomized). This includes acute lymphedema (occurs within first year after surgery) and chronic lymphedema. Some of those with acute lymphedema resolve with time, while others remain with lymphedema (chronic). Of these, 14 were from the intervention group (Group 1) and 11 were from the control group (Group 2). We predicted that after a 3-year followup for each study subject, we would observe a 60% reduction in the incidence of acute lymphedema in the intervention group as compared to the control group. For this second report, we are grouping all lymphedema patients together. Plan: As the study continues, the sample size of 158 evaluable patients will permit determination of acute and chronic lymphedema. The reporting of lymphedema during the first year after surgery is new information.**

**For the secondary endpoints of the study,**

**a) Infection rate: We have observed three infections for the first 21.5 months of subject participation with no differences between the groups.**

***b)*** **Scores and trends: In Table II, scores for QOL measures are listed. Group scores at each time point do not significantly differ. Total FACT-B scores was reported, the Physical Functioning Scale of the MOS-SF 36 was reported, and the sexuality subscale of CARES was reported here, using the T score that standardizes the scores. Plan: When all scoring is complete, subscales for each instrument will be tabulated to define reasons for the scores. In Table 3, longitudinal changes in the QOL scores over time thus far for each subject were calculated and reported for the group at specific time points. There was a decrease in FACT-B scores with time for group 1 but not group 2. For MOS-SF 36 reports, both groups decreased their scores within the first year with subsequent improvement. Finally, Group 1 subjects had a worsening of sexuality scores (increased) as compared to group 2. These are only interim observations but again provide additional information on postoperative breast cancer patients.**

**Plan: Compare the QOL scores in subgroup with lymphedema separately from those without lymphedema in the future.**

**c) Scores on Knowledge and compliance questionnaires: Further analysis must wait additional followup of accrued subjects. As followup continues, the compliance scores will be compared through 3 years of followup.**

**During this second annual year report, the Tasks in the Statement of Work are being accomplished and data are being collected as described in the study. The study objectives will be answered when at least three years of followup data (to occur during the five years of study) are collected. These data thus far confirm that the study should continue.**

*Task 12.* Analysis of data after 5th year, Months 61-65.
**Not yet applicable.**

*Task 13.* Annual report to USAMRMC, Months to be designated by USAMRMC.

a. Annual reports (Year 1,2,3,4) to summarize findings, scientific issues, and accomplishments.
**Year I and Year II reports submitted.**

b. Final report in the last year to report findings and accomplishments for the entire project.
**Not yet applicable.**

*Task 14.* Meeting in Baltimore, Maryland to disseminate results of DoD-sponsored Research during the second year, Month to be announced by USAMRMC.
**Planned for September, 2002.**

*Task 15.* Write journal articles. Submit abstract, Months 12-60+

a. Yearly opportunity to submit abstract to lymphedema and other professional meetings.
**Abstract to AACR submitted for Spring, 2002.**

b. Final report will be converted to journal format for submission.
**Not yet applicable.**

**Table 3: Longitudinal changes in quality of life questionnaires**
(FACT-B, MOS-SF-36, CARES)

| | N | Group 1 | N | Group 2 |
|---|---|---|---|---|
| **FACT-B (total score)** | | | | |
| 6-mon compare to 0 month change | 26 | 1.411±20.42 | 28 | 6.3612±24.07 |
| 12-mon compared to 0 month | 18 | -2.309±24.75 | 20 | 5.0054±19.73 |
| 24-month compare to 0 month | 4 | -8.063±10.02 | 8 | 2.375±17.63 |
| 36-month compared to 0-month | 0 | N/A | 0 | N/A |
| | | | | |
| **MOS SF-36 (total score)** | | | | |
| 6-mon compare to 0 month change | 22 | -0.729±11.01 | 23 | -2.924±13.37 |
| 12-mon compared to 0 month | 15 | -0.195±7.60 | 16 | 4.1531±15.35 |
| 24-month compare to 0 month | 3 | 3.1312±1.99 | 5 | 2.7232±7.66 |
| 36-month compared to 0-month | 0 | N/A | 0 | N/A |
| | | | | |
| **CARES (sexuality subscale)** | | | | |
| 6-mon compare to 0 month change | 11 | 1.3636±3.98 | 9 | -1.778±5.72 |
| 12-mon compared to 0 month | 7 | 1.4286±2.30 | | -1.333±5.41 |
| 24-month compare to 0 month | 2 | 7.0±1.41 | | -3.5±7.59 |
| 36-month compared to 0-month | | N/A | | N/A |

## KEY RESEARCH ACCOMPLISHMENTS

- **Lymphedema was detected in 32.9% of subjects over 21.5 months of the study.**
- **There is no difference in infection rates in the intervention group compared to the control group over 21.5 months of the study.**
- **The Quality of Life scores decreased over time for subjects in the intervention group compared to control group over 21.5 months of the study.**
- **Knowledge of lymphedema protection measures and compliance with protection measures was comparable between the intervention and control groups over 21.5 months of the study.**

**Discussion:**

1. **A separate analysis of acute lymphedema compared to chronic lymphedema will be reported when the study is completed. This is new information.**
2. **The subscales for each QOL instrument will be scored and compared to determine specific reasons for the trends in QOL scores over time for the intervention and control groups.**

3. **The longitudinal trends in scores for assessment of knowledge of lymphedema protection measures will be completed at the end of the study. Likewise, the compliance with protection measures will be compared over time at the end of the study.**

## REPORTABLE OUTCOMES

**From the AACR, 2002 meeting:**
**Abstract: "Does the extent of breast cancer surgery impact sexual and marital aspects of quality of life? "**

## CONCLUSIONS

1. **The lymphedema rate overall is greater than predicted in the literature (32.0%) thus far in the study, and requires further analyses based upon variables of education, type of surgery, infection rate, and occupation.**
2. **The quality of life decreases in the intervention group with time, with additional analyses required to determine specific reasons.**
3. **Knowledge of lymphedema protection is comparable between the intervention and control groups indicating possible effect of increased awareness in the general public.**

**"So What Section"**

**The awareness of lymphedema occurrence, protection, and treatment by many clinicians that are in contact with breast cancer survivors is not uniform. Furthermore, textbooks do not include enough detail regarding incidence, symptoms, measurement, and treatment, which leads to less attention to the survivor's observations. This study must be completed to rebut current opinion in the medical literature. It will "rock the boat" and challenge current practice. Already, lymphedema in the first year postoperatively is underreported and this study will be able to add to the literature. In order to do so, the data are being carefully collected, and are showing important trends already. The longitudinal collection of measurements in several dimensions (physical, quality of life, knowledge, behavior (compliance)) will provide strong data and conclusions that are absolutely necessary to shift established practices that have not really been the result of careful study. There are also several additional studies that will emanate from this study, with the potential to include additional disciplines in breast cancer research.**

## REFERENCES

n.a.

## APPENDICES

n.a.